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REMARKS

As of the present amendment, claims 1-11 and 29-50 are pending in the application, with claims 12-28 having been canceled without prejudice or disclaimer. Claims 1-11 and 29-37 were rejected and the specification objected to in the final Office action. In an Advisory Action dated May 16, 2003, the examiner withdrew the indefiniteness rejection of claim 36, but maintained the rejection of all claims on other grounds. The rejection is traversed, with claim 1 being amended herein and new claims 38-50 being added herein.

Explanation of the Amendments

The amendment to the Title has clear support in the application as filed on page 1, lines 3-5.

Claim 1 has been amended by specifying that the edge on the mandrel that separates the top surface and the contoured surfaces is a sharp edge. The term "sharp edge" is well supported in the application as filed, inasmuch as the term is used frequently throughout the present application in the context of various embodiments. One such embodiment and the advantages thereof are described on page 11, lines 1-20. A variation having a groove placed along the edge is described on page 11, lines 21-23. Another example is described with great detail on page 26, line 32 through page 27, line 8.

Claims 38-50 have been added pursuant to applicants' right to present the claimed subject matter in a reasonable number of claims of varying scope. These claims are fully supported by the present application as filed, including, for example, the material cited in the foregoing paragraph, as well as the material on page 18, lines 15-17; page 22, line 7 through page 23, line 19; page 29, line 25 through page 32, line 20; and so forth. The new claims contain no new matter.

Entry of all of the amendments is believed to proper and is respectfully requested.

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Request for Clarification of the Examiner's Objection to the Specification

In the final Office action, the examiner indicated in the Office Action Summary that the specification of the present application is objected to, but the undersigned could find no express explanation in the final Office action or the Advisory Action. The examiner is requested to clarify the nature of any objection.

General Statement on the Patentability of the Claims

Applicants will specifically address each of the rejections in a section to follow. However, as independent claim 1 as amended and independent claim 29 as originally filed contain the limitation "sharp edge," applicants wish to simplify the prosecution by commenting on the patentability of these claims due to this common limitation. Moreover, new independent claim 38 contains a limitation on line 11 pertaining to the "radius of curvature" of a boundary, to which the discussion of the "sharp edge" limitation has some relevance.

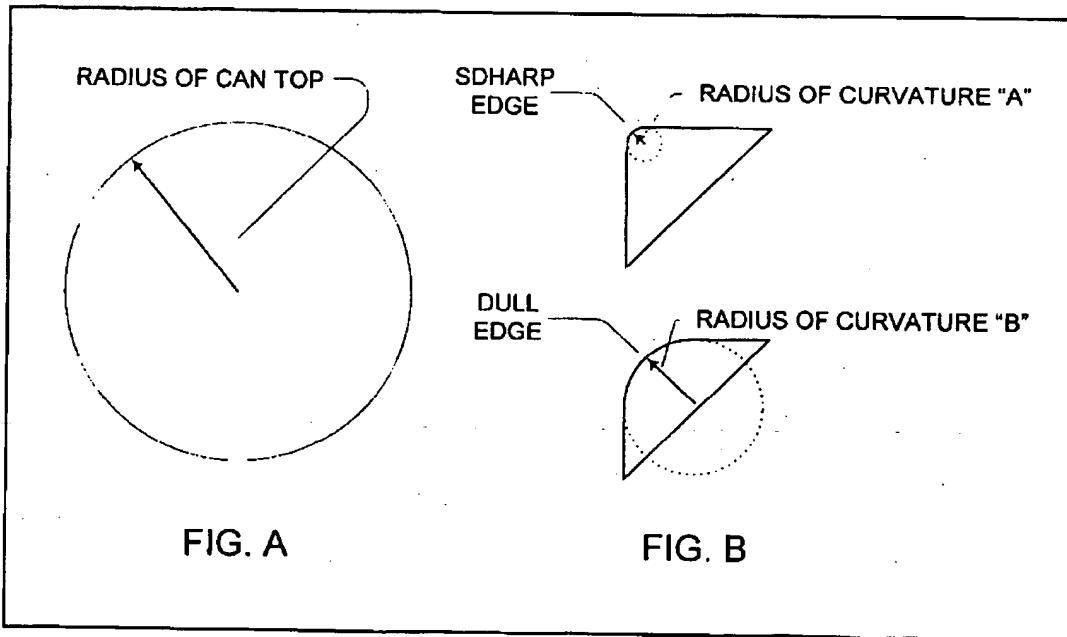
Before furnishing their detailed comments, Applicants wish to provide a clarification or perhaps a retraction of an argument relating to "sharp edge" made in the Amendment and Response Under 37 C.F.R. §1.116, which was filed on April 30, 2003. On page 5 of that document, applicants made the following statement regarding claim 36 in the last paragraph.

In paragraph 4 on page 2 of the Office Action, claim 36 was rejected under 35 U.S.C. § 112 second paragraph for being indefinite. The Applicants respectfully traverse this rejection. Support for the features of this claim can be found on at least page 27, lines 1-8 of the specification. The Applicants respectfully submit that a sharp edge can have a radius of curvature. For example, when a can of vegetables is opened and the top is removed by a can opener, the removed top demonstrates a sharp edge having a radius of curvature. It is understood that the radius of curvature may reside along a different axis than an axis chosen to demonstrate that an edge is sharp.

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The last sentence stating that "the radius of curvature may reside along a different axis than an axis chosen to demonstrate that an edge is sharp" may not be correct, or at least may be ambiguous. The phrase in claim 36 "wherein the sharp edge has a radius of curvature" should *not* be understood to pertain to the relationship shown in Fig. A below. In Fig. A, the circle represents a can top (the "removed top" per applicants' prior remarks) in plan view, and the arrow is the radius of the can top, not the radius of curvature of the edge. Rather, the phrase "wherein the sharp edge has a radius of curvature" is better understood with reference to Fig. B below. Fig. B shows two different edges in cross-section (cross-hatching omitted for clarity). While these edges are formed by surfaces that meet at the same 90 degree angle, one edge has a radius of curvature A and another edge has a radius of curvature B. For purposes of explanation only and not to imply any limitation of scale, the edge having the radius of curvature A might be considered to be a sharp edge, while the edge having the radius of curvature B might be considered to be an edge that is not sharp, i.e., a dull edge.



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Because it is clear how a sharp edge can have a radius of curvature, claim 36 should not be subject to a section 112 rejection.

Having provided the clarification/retraction, Applicants now comment on how the "sharp edge" limitation renders independent claims 1 and 29 and all claims dependent therefrom patentable. The reason is that none of the applied references disclose or teach a sharp edge as set forth in claims 1 and 29. First and foremost, none of these references specifies that the edges of their forms are themselves sharp. Hence, the requisite teaching is entirely absent. Moreover, no such teaching may be inferred for the simple reason that all of these references either require trimming the polymer structures *prior to removal*, or removing the polymer structures from their respective forms *in one piece*. If the edges of the forms disclosed in the applied references were themselves sharp, the polymer structures either would not have to be trimmed on the form, or could not be removed from the form in one piece. The specific teachings of the applied references are as follows.

- The Jansen et al. '113 patent teaches trimming the closing elements on the dip mould surfaces 5 prior to removal of the final heart valve, at column 7, lines 19-23.
- The NL 1008349 patent teaches a mandrel that comprises a cylindrical lower mandrel half-section and a cylindrical upper mandrel half-section. The examiner has not cited the NL patent for any disclosure or teaching relevant to the sharpness of the edge.
- The Pierce et al. '127 patent teaches removing the entire stent with the leaves formed thereon, and thereafter separating the leaves by cutting, at column 4, lines 8-13.
- The Moe et al. '331 patent contains no teachings pertinent to the "sharp edge" issue.
- The Stockum '867 patent is concerned with avoiding imperfections in a rubber glove and improving the releasability thereof from a glove form. While the patent discloses a form having "smaller radii of the edges," column 3, line 7, it will be appreciated that the term "smaller" is a relative term, whereby the smaller edges are being compared to large and bulky edges in the prior art of glove making, see column 2, lines 37-39.

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In fact, Stockum teaches away from making these smaller edges sharp, in that "the edge is preferably smoothly curved **to avoid any sharp edges** that could result in pinholes or other failures in the elastomeric material deposited on form 10," column 5, lines 4-7 (emphasis supplied). This teaching-away is unambiguous.

- The Hennig et al. '442 patent teaches removing the core from the case after drying, and then surface finishing the various portions and removing burrs along the edges, at column 3, line 53 through column 4, line 5.

New claim 38 contains the limitation: "wherein the contoured surface section intersects the end surface to form a boundary that corresponds to the free edge of the leaflet, the boundary generally having a radius of curvature comparable to a coating thickness predetermined by the wetting property of the contoured surface section and the end surface adjacent region, and by the viscosity of the polymer composition." This limitation is not taught or suggested in any of the applied references.

As claim 1 as amended and claims 29 and 38 are neither anticipated by nor obvious over the applied references, the rejection of claims 1 and 29 should be withdrawn and claims 1, 29 and 38 passed on to allowance. All claims dependent from independent claims 1, 29 and 38 are allowable as well, since they include all of the limitations of the independent claims from which they depend and are patentable for the same reasons as set forth above. Moreover, while the dependent claims may recite additional limitations of independent patentable significance, extensive discussion of their independent patentability is moot in view of the remarks made in connection with the independent claims.

Comments Traversing Claim Rejections Under 35 USC § 102

In paragraph 6 on page 3 of the final Office action, claims 1-2, 5-7 and 10 were rejected under 35 U.S.C. §102 (b) as being anticipated by Jansen, et al. (U.S. Patent No. 5,116,564). Applicants respectfully traverse the rejections for at least the reasons discussed above. Additionally, claim 1 provides that the mandrel edge corresponds to the free edge of the leaflets, whereas Jansen et al. does not show this (applicants

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believe that the edge of the closing element 12 shown in Jansen's Fig. 3 appears elevated because of the perspective angle of the drawing, but is in fact not elevated). Applicants respectfully request that the rejection of claims 1, 2, 5-7 and 10 be withdrawn.

In paragraph 7 on page 3 of the final Office action, claims 1-2, 5-7, 10, and 30 were rejected under 35 U.S.C. §102 (b) as being anticipated by NL 1008349. Applicants respectfully traverse the rejections for at least the reasons discussed above. While ambiguities in the Fig. 8A drawing make a specific response difficult, Fig. 8A discloses nothing about a sharp edge. Applicants respectfully request that the rejection of claims 1, 2, 5-7, 10 and 30 be withdrawn.

In paragraph 8 on page 4 of the final Office action, claims 1, 8, 11, 29, and 31 are rejected under 35 U.S.C. §102 (b) as being anticipated by Pierce, et al. (U.S. Patent No. 4,364,127). Applicants respectfully traverse the rejections for at least for the reasons discussed above. Additionally, Pierce does not disclose a mandrel edge corresponding to a free edge of the leaflet (claim 1) or where adjacent leaflets meet (claim 29). As shown in Fig. 11, the free edge of the leaflet (40) is along the middle of the top of shim 35, which is a flat surface and not an edge. Applicants respectfully request that the rejection of claims 1, 8, 11, 29 and 31 be withdrawn.

Comments Traversing Claim Rejections Under 35 USC § 103

In paragraph 10 on page 5 of the final Office action, claims 3-4, 9, and 32-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jansen, et al. or NL 1008349 in view of Moe, et al. (U.S. Patent No. 6,174,331) and Stockum (U.S. Patent No. 4,135,867). In paragraph 11 on page 7 of the Office Action, claim 35 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Jansen, et al. or NL 1008349 in view of Hennig (U.S. Patent No. 4,575,442). In paragraph 12 on page 8 of the Office Action, claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierce, et al. in view of Moe, et al. In paragraph 13 on page 9 of the Office Action, claim 37 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierce, et al. in view of Hennig, et al. Applicants respectfully traverse the rejections because independent claims 1 and 29 are not obvious for at least for the reasons discussed above, and the rejected

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dependent claims necessarily include the limitations thereof. Additionally, claims 3, 4, 34 and 36 contain limitations on the radius of curvature that are not disclosed and are in no way taught or suggested by the applied references.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at 952-253-4134.

Respectfully submitted,

Altera Law Group, LLC
Customer No. 22865

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By:

Hallie A. Finucane
Hallie A. Finucane
Reg. No. 33,172
HAF/mar